UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
(ATLANTA DIVISION)

SUSAN ALLEN, Plaintiff, BAYER HEALTHCARE PHARMACEUTICALS,INC., Defendant.	COMPLAINT AND JURY DEMAND Civil Action No.:

Plaintiff, Susan Allen (referred to as "Plaintiff"), by and through her attorneys, **CHILDERS, SCHLUETER & SMITH, L.L.C.,** on behalf of herself individually, hereby sues the defendant, **BAYER HEALTHCARE PHARMACEUTICALS, INC.** (hereinafter referred to as "Defendant") and upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal place of business in states other than the state in which the named Plaintiff resides.

2. On April 8, 2013, the Unites States Judicial Panel on Multidistrict Litigation entered its Transfer Order in the matter "Mirena IUD Products Liability Litigation," MDL No. 2434, transferring all Mirena IUD cases alleging perforation, embedment, or migration of the device that were pending in the federal courts to the United States District Court for the Southern

District of New York, before the Hon. Cathy Seibel. Plaintiff believes that the present case is appropriate for inclusion in MDL 2434, and should be transferred to the Southern District of New York after the JPML issues a Conditional Transfer Order (CTO) seeking the transfer of this case to MDL 2434.

BACKGROUND

3. This is an action for damages suffered by Plaintiff, Susan Allen, who used the intrauterine device (hereinafter referred to as "IUD") MIRENA® (hereinafter referred to as "MIRENA®" or "the subject product").

4. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed MIRENA®.

5. When warning of safety and risks of MIRENA®, Defendant negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff and the public in general, that MIRENA® had been tested and was found to be safe and/or effective for its indicated use.

6. Defendant concealed its knowledge of MIRENA's® defects, from Plaintiff, the FDA, the public in general and/or the medical community specifically.

7. These representations were made by Defendant with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, implant and/or purchase MIRENA® for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

8. Defendant negligently and improperly failed to perform sufficient tests, if any, on women using MIRENA® during clinical trials, forcing Plaintiff, and her physicians, hospitals, and/or the FDA, to rely on safety information that applies to other contraceptives, which does not entirely and/or necessarily apply to the MIRENA® whatsoever.

9. Defendant was negligent in failing to adhere to and/or take into consideration warnings from the FDA, who determined that the Defendant was misleading the public in general, and the medical community in particular, through the use of advertisements which overstated the efficacy of MIRENA® and minimized the serious risks of the product.

10. As a result of the defective nature of MIRENA®, those persons who use and/or used and relied on MIRENA® have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

11. Plaintiff herein has sustained certain of the above health consequences due to her use of MIRENA®.

12. Defendant concealed its knowledge of the defects in its products from the Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

13. Consequently, Plaintiff seeks compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper, as a

result of her use of the MIRENA®, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at greatly increased risk of serious and dangerous side effects including, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

14. Plaintiff is a resident and citizen of Peyton, Colorado located in El Paso County.

15. Plaintiff avers that the federal judicial district in which Plaintiff's Mirena was inserted was District of Colorado; and the federal judicial district in which Plaintiff currently resides is District of Colorado. The Plaintiff requests that the law of State of Colorado be treated as governing law for purposes of choice of law analysis. Plaintiff(s) further request(s) that the Court apply the substantive law of State of Colorado to liability determinations unrelated to punitive damages.

PARTY DEFENDANT

16. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. (hereinafter also referred to as "BAYER" or "Defendant") is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Pursuant to the Agreed Order Regarding Proper Party-Defendant and Abbreviated Service Procedures for Service Upon Defendant Bayer HealthCare Pharmaceuticals Inc. entered by the Hon. Cathy Seibel of the U.S.

District Court for the Southern District of New York on July 17, 2013, BAYER may be properly served with Summons and Complaint via Certified Mail, Return Receipt Requested, addressed to: SOP Department, Corporation Service Company, Suite 400, 2711 Centerville Road, Wilmington, DE 19808.

17. Upon information and belief, at all relevant times Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. has transacted and conducted business in the State of Georgia and the State of Colorado, and derived substantial revenue from interstate commerce.

18. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. expected or should have expected that its acts would have consequences within the United States of America, and the State of Georgia and the State of Colorado in particular, and derived substantial revenue from interstate commerce.

19. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute MIRENA® as an intrauterine contraceptive system.

20. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is the holder of the approved New Drug Application ("NDA") for contraceptive device MIRENA®.

21. At all times alleged herein, Defendant includes and included any and all parents, subsidiaries, affiliates, division, franchises, partners, joint venturers, and organizational unites of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

22. At all times relevant, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, MIRENA®.

FACTUAL ALLEGATIONS

23. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein, and further alleges as follows:

24. MIRENA® is an intrauterine contraceptive system made of flexible plastic that is inserted by a healthcare provider during an office visit.

25. The federal Food and Drug Administration (FDA) approved Defendant's NDA for MIRENA® in December 2000. Today, millions of women in the United States use MIRENA®. It has been used by more the 15 million women worldwide.

26. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendant admits "[i]t is not known exactly how MIRENA® works," but provided that MIRENA® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

27. The MIRENA® intrauterine system (IUS) is designed to be placed within seven (7) days of the first day of menstruation and approved to remain in the uterus for up to five years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

28. The package labeling recommends that MIRENA® be used in women who have had at least one child, suggesting that carrying a child to term may be complicated after MIRENA® use.

29. MIRENA®'s label does not warn about spontaneous migration of the IUD, but only states that migration may occur if the uterus is perforated during insertion.

30. Defendant has failed to alter MIRENA®'s product packaging to reflect the growing number of MedWatch Adverse Event reports related to embedment of and perforation through the uterine lining and/or migration of the IUD through the uterine lining after the period of insertion.

31. Defendant has a history of overstating the efficacy of MIRENA® while understating the potential safety concerns.

32. In or around March 2009, the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) issued a warning regarding Defendant's advertising materials for MIRENA® that constituted misbranding of the IUD in violation of the Federal Food, Drug and Cosmetic Act and FDA implementing regulations.

33. Specifically, DDMAC pointed out that BAYER failed to communicate any risk information, inadequately communicated MIRENA®'s indications, and overstated the efficacy associated with the use of MIRENA® in Bayer-sponsored on internet search engines.

34. DDMAC requested that BAYER immediately cease the dissemination of the violative materials.

35. Subsequently, in or around December 2009, Defendant was again contacted by DDMAC regarding a consumer-directed program entitled "MIRENA® Simple Style Statements

Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central," a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendant.

36. This "Simple Style" program represented that MIRENA® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined that these claims were unsubstantiated and, in fact, pointed out that MIRENA®'s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

37. The "Simple Style" program script also intimated that MIRENA® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that MIRENA® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

38. The portion of the "Simple Style" script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on MIRENA®.

39. Finally, Defendant falsely claimed that Defendant's system required no compliance with a monthly routine, in contradiction of patient instructions.

40. As a result of Defendant's violation of the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations, the FDA ordered BAYER to cease use of the violative materials.

CASE-SPECIFIC ALLEGATIONS

41. Plaintiff is 35 years old.

42. Plaintiff had a MIRENA® IUD inserted, tolerated the procedure well, and neither Plaintiff nor her medical provider had any reason to suspect that the MIRENA® perforated her uterus.

43. Plaintiff's MIRENA® later perforated her uterus, migrated, and/or embedded outside of Plaintiff's uterus.

44. As a result of said perforation, migration, and/or embedment, Plaintiff was required to undergo surgery to remove the MIRENA® from her body.

45. As alleged herein, as a direct and proximate result of the Defendant's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the subject product, Plaintiff suffered severe and permanent physical injuries, and has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from the Defendant as alleged herein.

FEDERAL REQUIREMENTS

46. Defendant had an obligation to comply with the law in the manufacture, design and sale of MIRENA®.

47. Upon information and belief, Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*

48. With respect to MIRENA®, Defendant, upon information and belief, failed to comply with federal standards applicable to the sale of prescription drugs including but not limited to one or more of the following violations:

a. MIRENA® is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements.

b. MIRENA® is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for MIRENA® and such deviations are not plainly stated on their labels.

c. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because, among other things, its labeling is false or misleading.

d. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because words, statements or other information required by or under authority of 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because the labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe methods or duration of administration or application in such manner and form as are necessary for the protection of users.

f. MIRENA® is misbranded pursuant to U.S.C.§ 352 because it is dangerous to health when used in the manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

g. MIRENA® does not contain adequate directions for use pursuant to 21 C.F.R. § 201.5 because, among other reasons of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes or uses for which it is intended, including conditions, purposes or uses for which it is prescribed, recommended or suggested in their oral, written, printed or graphic advertising, and conditions, purposes or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application and/or (d) route or method of administration or application.

h. The Defendant violated 21 C.F.R. § 201.56 because MIRENA®'s labeling was not informative and accurate.

i. MIRENA® is misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated and new information became available that caused the labeling to become inaccurate, false or misleading.

j. The Defendant violated 21 C.F.R. § 201.57 by failing to provide information that is important to the safe and effective use of the device including the potential of MIRENA® to migrate through the uterine lining or wall not related to insertion, and the need for regular and/or consistent monitoring to ensure that the device has not migrated.

k. The Defendant violated 21 C.F.R. § 201.57 because it failed to identify specific tests needed for selection or monitoring of patients who used MIRENA®.

l. MIRENA® is mislabeled pursuant to 21 C.F.R.§ 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it and steps that should be taken if they occur.

m. MIRENA® is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the contraceptive device.

n. The Defendant violated 21 C.F.R. § 201.57 because the possibility that the device could migrate through the uterine lining and/or wall not associated with insertion is significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendant failed to list the risk of migration before the other adverse reactions on the labeling of MIRENA®.

o. MIRENA® violates 21 C.F.R. § 210.1 because the process by which it was manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing or holding of a contraceptive device to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that it purports or is represented to possess.

p. MIRENA® violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

q. MIRENA® violates 21 C.F.R. § 211.165 because the test methods employed by the Defendant are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity and/or reproducibility of test methods have not been properly established and documented.

r. MIRENA® violates 21 C.F.R. § 211.165 in that it fails to meet established standards or specifications and any other relevant quality control criteria.

s. MIRENA® violates 21 C.F.R. § 211.198 because the written procedures describing the handling of all written and oral complaints were not followed.

t. MIRENA® violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

u. The Defendant violated 21 C.F.R. § 310.303 because it failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

v. The Defendant violated 21 C.F.R. §310.305 and § 314.80 by failing to report adverse events associated with MIRENA® as soon as possible or at least within 15 days of the initial receipt by the Defendant of the adverse event report.

w. The Defendant violated 21 C.F.R. § 310.305 and § 314.80 by failing to conduct an investigation of each adverse event associated with MIRENA® evaluating the cause of the adverse event.

x. The Defendant violated 21 C.F.R. §310.305 and § 314.80 by failing to promptly investigate all serious, unexpected adverse experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

y. The Defendant violated 21 C.F.R. § 310.305 and § 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse experiences.

z. The Defendant violated 21 C.F.R. § 310.305 and § 314.80 by failing to identify the reports they submitted properly such as by labeling them as “15-day Alert report” or “15-day Alert report follow-up.”

aa. The Defendant violated 21 C.F.R. § 312.32 because it failed to review all information relevant to the safety of MIRENA® or otherwise received by the Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers as well as reports from foreign regulatory authorities that have not already been reported to the agency by the sponsor.

bb. The Defendant violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse experience not already reported under the post-marketing 15-day alert report and/or (c) a history of actions taken since the last report because of adverse experiences (for example labeling changes or studies initiated).

cc. The Defendant violated 21 C.F.R. § 314.80 by failing to submit a copy of a published article from scientific or medical journals along with one or more 15-day alert reports based on information from the scientific literature.

49. Defendant failed to meet the standard of care set by the above statutes and regulations which were intended for the benefit of individual consumers such as Plaintiff making the Defendant liable.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(NEGLIGENCE)

50. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

51. Defendant had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of MIRENA® into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

52. Defendant failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of MIRENA® into interstate commerce in that Defendant knew or should have known that using MIRENA® created a high risk of unreasonable, dangerous side effects, including, inter alia, perforation, migration, embedment, ectopic

pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

53. The negligence of the Defendant, its agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing MIRENA® without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing MIRENA® without adequately testing it;

c. Not conducting sufficient testing programs to determine whether or not MIRENA® was safe for use; in that Defendant herein knew or should have known that MIRENA® was unsafe and unfit for use by reason of the dangers to its users;

d. Selling MIRENA® without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of MIRENA®;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, MIRENA®;

g. Failing to test MIRENA® and/or failing to adequately, sufficiently and properly test MIRENA®.

h. Negligently advertising and recommending the use of MIRENA® without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that MIRENA® was safe for use for its intended purpose, when, in fact, it was unsafe;

j. Negligently representing that MIRENA® had equivalent safety and efficacy as other forms of birth control/contraception;

k. Negligently designing MIRENA® in a manner which was dangerous to its users;

l. Negligently manufacturing MIRENA® in a manner which was dangerous to its users;

m. Negligently producing MIRENA® in a manner which was dangerous to its users;

n. Negligently assembling MIRENA® in a manner which was dangerous to its users;

o. Concealing information concerning FDA warnings from the Plaintiff in knowing that MIRENA® was unsafe, dangerous, and/or non-conforming with FDA regulations; and

p. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of MIRENA® compared to other forms of contraception.

54. Defendant under-reported, underestimated and downplayed the serious dangers of MIRENA®.

55. Defendant negligently compared the safety risk and/or dangers of MIRENA® with other forms of contraception.

56. Defendant was negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of MIRENA® in that it:

a. Failed to use due care in designing and manufacturing MIRENA® so as to avoid the aforementioned risks to individuals when MIRENA® was used for contraceptive purposes;

b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of MIRENA®;

c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of MIRENA®;

d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning MIRENA®;

e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of MIRENA®;

g. Failed to warn Plaintiff, prior to actively encouraging the sale of MIRENA®, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

h. Was otherwise careless and/or negligent.

57. Despite the fact that Defendant knew or should have known that MIRENA® caused unreasonably dangerous side effects, Defendant continued and continues to market, manufacture, distribute and/or sell MIRENA® to consumers, including the Plaintiff.

58. Defendant knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care, as set forth above.

59. Defendant's negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and/or will continue to suffer.

60. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

61. As a result of the foregoing acts and omissions, the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff may in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)

62. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

63. At all times herein mentioned, the Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed MIRENA® as hereinabove described that was used by the Plaintiff.

64. At those times, MIRENA® was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

65. At those times, MIRENA® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

66. MIRENA® is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

67. At all times material to this action, MIRENA® was expected to reach, and did reach, consumers in all States and Territories throughout the United States, including the Plaintiff herein, without substantial change in the condition in which it was sold.

68. At all times material to this action, MIRENA® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, MIRENA® contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to the risks of perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences;

b. When placed in the stream of commerce, MIRENA® was defective in design and formulation, making the use of MIRENA® more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other contraceptive devices, medications and similar drugs on the market for the prevention of pregnancy;

c. The subject product's design defects existed before it left the control of the Defendant;

d. MIRENA® was insufficiently tested;

e. MIRENA® caused harmful side effects that outweighed any potential utility; and

f. MIRENA® was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including the Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendant strictly liable to Plaintiff.

69. The Plaintiff was prescribed and used the subject product for its intended purpose.

70. Defendant created a product that is unreasonably dangerous for its normal, intended use.

71. Defendant knew, or should have known that at all times herein mentioned its MIRENA® was in a defective condition, and was and is inherently dangerous and unsafe.

72. Defendant, with this knowledge, voluntarily designed its MIRENA® in a dangerous condition for use by the public, and in particular the Plaintiff.

73. In addition, at the time the subject product left the control of the Defendant, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

74. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendant is therefore strictly liable for the injuries sustained by the Plaintiff.

75. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies

and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

76. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT)

77. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

78. At all times herein mentioned, the Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed MIRENA® as hereinabove described that was used by the Plaintiff.

79. At those times, MIRENA® was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

80. At those times, MIRENA® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

81. The contraceptive, MIRENA®, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant reached its intended users in the same defective and unreasonably dangerous condition in which the Defendant's MIRENA® was manufactured.

82. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendant is therefore strictly liable for the injuries sustained by the Plaintiff.

83. The Plaintiff was prescribed and used the subject product for its intended purpose.

84. The Plaintiff could not by the exercise of reasonable care, have discovered MIRENA®'s defects herein mentioned and perceived its danger.

85. At all times material to this action, MIRENA® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, MIRENA® contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendant;

c. The subject product was not made in accordance with the Defendant's specifications or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of the Defendant.

86. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

87. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)

88. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

89. The contraceptive, MIRENA®, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate warnings and/or inadequate testing.

90. MIRENA® was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert consumers, including the Plaintiff herein, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to cause perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

91. The Plaintiff was prescribed and used the subject product for its intended purpose.

92. The Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

93. The Defendant, as manufacturer and/or distributor of the subject product, is held to the level of knowledge of an expert in the field.

94. The warnings that were given by the Defendant were not accurate, clear and/or were ambiguous.

95. The warnings that were given by the Defendant failed to properly warn physicians of the increased risks of perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies

and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

96. The Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendant.

97. The Defendant had a continuing duty to warn the Plaintiff of the dangers associated with the subject product.

98. By reason of the foregoing, the Defendant has become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, MIRENA®.

99. Defendant's inadequate warnings of MIRENA® were acts that amount to willful, wanton, and/or reckless conduct by Defendant.

100. Said defects in Defendant's product MIRENA® were a substantial factor in causing Plaintiff's injuries.

101. Had the Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

102. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

103. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(BREACH OF EXPRESS WARRANTY)

104. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

105. Defendant expressly warranted to Plaintiff that MIRENA® was safe and well accepted by users.

106. The contraceptive MIRENA® does not conform to these express representations because MIRENA® is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendant. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

107. Plaintiff did rely on the express warranties of the Defendant herein.

108. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendant for use of MIRENA® in recommending, prescribing, and/or implanting MIRENA®.

109. The Defendant herein breached the aforesaid express warranties, as its product MIRENA® was defective.

110. Defendant expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that MIRENA® was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of other hormonal contraceptives, intrauterine devices and other forms of birth control therapy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

111. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that MIRENA® was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendant.

112. As a result of the foregoing acts and/or omissions the Plaintiff, was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

113. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendant's MIRENA® IUD.

114. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(BREACH OF IMPLIED WARRANTIES)

115. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

116. At all times herein mentioned, the Defendant manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold MIRENA® for use in contraception.

117. At the time Defendant marketed, sold, and distributed MIRENA® for use by Plaintiff, Defendant knew of the use for which MIRENA® was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

118. The Defendant impliedly represented and warranted to the users of MIRENA® and their physicians, healthcare providers, and/or the FDA that MIRENA® was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

119. Said representations and warranties aforementioned were false, misleading, and inaccurate in that MIRENA® was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

120. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

121. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendant as to whether MIRENA® was of merchantable quality and safe and fit for its intended use.

122. The contraceptive MIRENA® was injected into the stream of commerce by the Defendant in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

123. The Defendant breached the aforesaid implied warranties, as its product MIRENA® was not fit for its intended purposes and uses.

124. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

125. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(FRAUDULENT MISREPRESENTATION)

126. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

127. The Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, MIRENA®, had been tested and was found to be safe and/or effective for contraceptive purposes.

128. That representations made by Defendant were, in fact, false.

129. When said representations were made by Defendant, it knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

130. These representations were made by Defendant with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and

healthcare community in particular, to recommend, prescribe, implant and/or purchase said product, MIRENA®, for use as a means of birth control, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

131. At the time the aforesaid representations were made by the Defendant and, at the time the Plaintiff used MIRENA®, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

132. In reliance upon said representations, the Plaintiff was induced to and did use MIRENA®, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

133. Defendant knew and was aware or should have been aware that MIRENA® had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

134. Defendant knew or should have known that MIRENA® had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

135. Defendant brought MIRENA® to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

136. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain

and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

137. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(FRAUDULENT CONCEALMENT)

138. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

139. At all times during the course of dealing between Defendant and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the safety of MIRENA® for its intended use.

140. At all times during the course of dealing between Defendant and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the efficacy and risks associated with the use of MIRENA®.

141. Defendant knew or was reckless in not knowing that its representations were false.

142. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant fraudulently concealed and intentionally omitted the following material information:

a. that MIRENA® was not as safe as other forms of contraception;

b. that the risks of adverse events with MIRENA® were higher than those with other forms of birth control, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

c. that the risks of adverse events with MIRENA® were not adequately tested and/or known by Defendant;

d. that Defendant was aware of dangers in MIRENA®, in addition to and above and beyond those associated with other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

e. that MIRENA® was defective, and that it caused dangerous side effects, including but not limited to perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause, in a much more and significant rate than other forms of birth control, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

f. that patients needed to be monitored more regularly than normal while using MIRENA®;

g. that MIRENA® was manufactured negligently;

h. that MIRENA® was manufactured defectively;

i. that MIRENA® was manufactured improperly;

j. that MIRENA® was designed negligently;

k. that MIRENA® was designed defectively; and

l. that MIRENA® was designed improperly.

143. Defendant was under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of MIRENA®, including but not limited to the heightened risks of perforation, migration, embedment, ectopic pregnancy,

intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause and infertility.

144. Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used MIRENA®, including the Plaintiff, in particular.

145. Defendant's concealment and omissions of material facts concerning, inter alia, the safety of MIRENA® was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and her physicians, hospitals and healthcare providers into reliance, continued use of MIRENA®, and actions thereon, and to cause them to purchase, prescribe, and/or implant MIRENA® and/or use the product.

146. Defendant knew that Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding MIRENA®, as set forth herein.

147. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

148. As a result of the foregoing acts and omissions the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as

well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

149. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(NEGLIGENT MISREPRESENTATION)

150. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

151. Defendant represented to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that MIRENA® had been tested, and had been found to be safe and effective for birth control.

152. The representations made by Defendant were, in fact, false.

153. Defendant failed to exercise ordinary care in the representation of MIRENA®, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendant negligently misrepresented MIRENA®'s high risk of unreasonable, dangerous side effects.

154. Defendant breached its duty in representing MIRENA®'s serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

155. As a result of the negligent misrepresentations set forth hereinabove, Defendant knew and was aware, or should have known, that MIRENA® had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause, infertility as well as other severe and personal injuries which are permanent and lasting in nature.

156. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(FRAUD AND DECEIT)

157. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

158. Defendant conducted research and used MIRENA® as part of their research.

159. As a result of Defendant's research and testing, or lack thereof, Defendant blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that MIRENA® was safe and effective for use as a means of providing birth control.

160. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

161. Defendant had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their respective healthcare providers and/or the FDA.

162. The information distributed to the public, the FDA, and the Plaintiff by Defendant, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media, contained material representations of fact and/or omissions.

163. The information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included representations that Defendant's MIRENA® was safe and effective for use as a form of birth control.

164. The information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included representations that Defendant's MIRENA® carried the same risks, hazards, and/or dangers as other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

165. The information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included representations that Defendant's MIRENA® was more

effective in treating the symptoms of heavy menstrual bleeding, encouraging the use of MIRENA® in circumstances other than those in which the product has been approved, over-promises the benefits and minimizes the risk associated with MIRENA®.

166. The information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included false representations that MIRENA® was not injurious to the health and/or safety of its intended users.

167. The information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included false representations that MIRENA® was no more potentially injurious to the health and/or safety of its intended than other forms of other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

168. Defendant's representations were all false and misleading.

169. Upon information and belief, Defendant intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that MIRENA® was not safe as a means of contraception and/or was not as safe as other means of contraception, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

170. Defendant intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of MIRENA®, specifically but not limited to MIRENA® not having dangerous and serious health and/or safety concerns.

171. Defendant intentionally made material representations to the FDA and the public in general, including the medical profession and the Plaintiff, regarding the safety of MIRENA®,

specifically but not limited to MIRENA® being as safe a means of birth control as other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

172. It was the purpose of Defendant in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of MIRENA® and induce the public, and/or the Plaintiff to purchase, request, implant, prescribe, recommend, and/or continue to use MIRENA®.

173. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that MIRENA® was fit and safe for use as birth control.

174. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that MIRENA® was fit and safe for use as birth control and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

175. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that MIRENA® did not present serious health and/or safety risks.

176. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that MIRENA® did not present health and/or safety risks greater than other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

177. These representations, and others, made by Defendant were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

178. That these representations, and others, made by Defendant, were made with the intention of deceiving and defrauding the Plaintiff, including her healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her healthcare professionals to rely upon misrepresentations and caused the Plaintiff and/or her healthcare professionals to purchase, use, rely on, request, implant, recommend, and/or prescribe MIRENA®.

179. Defendant recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of MIRENA® to the public at large, and the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

180. Defendant willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of MIRENA® by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of MIRENA®.

181. Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on MIRENA® and/or that her healthcare providers would implant, prescribe, and/or recommend the same.

182. Defendant, through its public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her healthcare professionals would rely upon the information being disseminated.

183. Defendant utilized direct to consumer adverting to market, promote, and/or advertise MIRENA®.

184. Plaintiff and/or her healthcare professionals did in fact rely on and believe the Defendant's representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of birth control and were thereby induced to purchase, use and rely on Defendant's product MIRENA®.

185. At the time the representations were made, the Plaintiff and/or her healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of MIRENA®.

186. Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant, nor could the Plaintiff with reasonable diligence have discovered the true facts.

187. Had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of MIRENA®, Plaintiff would not have purchased, used and/or relied on Defendant's product MIRENA®.

188. Defendant's aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

189. As a result of the foregoing acts and omissions Plaintiff was caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia,

perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

190. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

ELEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANT
(PUNITIVE DAMAGES)

191. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

192. At all times material hereto, the Defendant knew or should have known that the subject product was inherently more dangerous than alternative methods of birth control.

193. At all times material hereto, the Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

194. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff herein, concerning the safety of the subject product.

195. At all times material hereto, the Defendant knew and recklessly disregarded the fact that MIRENA® causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control.

196. Notwithstanding the foregoing, the Defendant continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effects when there were safer alternative methods of birth control.

197. The Defendant knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by MIRENA®.

198. Defendant intentionally concealed and/or recklessly failed to disclose to the public, including Plaintiff herein, the potentially life threatening side effects of MIRENA® in order to ensure continued and increased sales.

199. The Defendant's intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the subject product against its benefits.

200. As a direct and proximate result of the Defendant's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has

incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future.

201. The aforesaid conduct of Defendant intentional, willful wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that Defendant acted only out of self interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiffs as provided under O.C.G.A. § 51-12-5.1 and/or other applicable laws. Accordingly, punitive damages should be imposed against Defendant pursuant O.C.G.A. § 51-12-5.1 and/or others applicable laws, to punish and deter Defendant from repeating or continuing such unlawful conduct.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays:

(a) That process issue according to law;

(b) That Defendant be served with a copy of Plaintiff's Complaint For Damages and show cause why the prayers for relief requested by Plaintiff herein should not be granted;

(c) That Plaintiff be granted a **TRIAL BY JURY** in this matter;

(d) That the Court enter a judgment against Defendant for all general and compensatory damages allowable to Plaintiff;

(e) That the Court enter a judgment against Defendant for all special damages allowable to Plaintiff;

(f) That the Court enter a judgment against Defendant serving to award Plaintiff punitive damages under the provisions of O.C.G.A. § 51-12-5.1 and/or other applicable laws;

(g) That the Court enter a judgment against Defendant for all other relief sought by Plaintiff under this Complaint;

(h) That the costs of this action be cast upon Defendant; and

(i) That the Court grant Plaintiff such further relief which the Court deems just and appropriate.

Dated: 1st day of May 2015

/s/: Richard R. Schlueter

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